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# Informed Consent

## Clinical Trial Subjects

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# Presentation Topics

- Legal Framework
  - Key Reference Documents
  - Key Requirements
  - National Specific Considerations
- Inspection
  - Aspects Reviewed
  - Common Deficiencies



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# Informed Consent

‘A process by which a subject **voluntarily** confirms his or her willingness to participate in a particular trial, after having been **informed of all aspects of the trial** that are relevant to the subject’s decision to participate. Informed consent is **documented by means of a written, signed and dated** informed consent form’



*ICH GCP 1.28*



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# Legal Framework

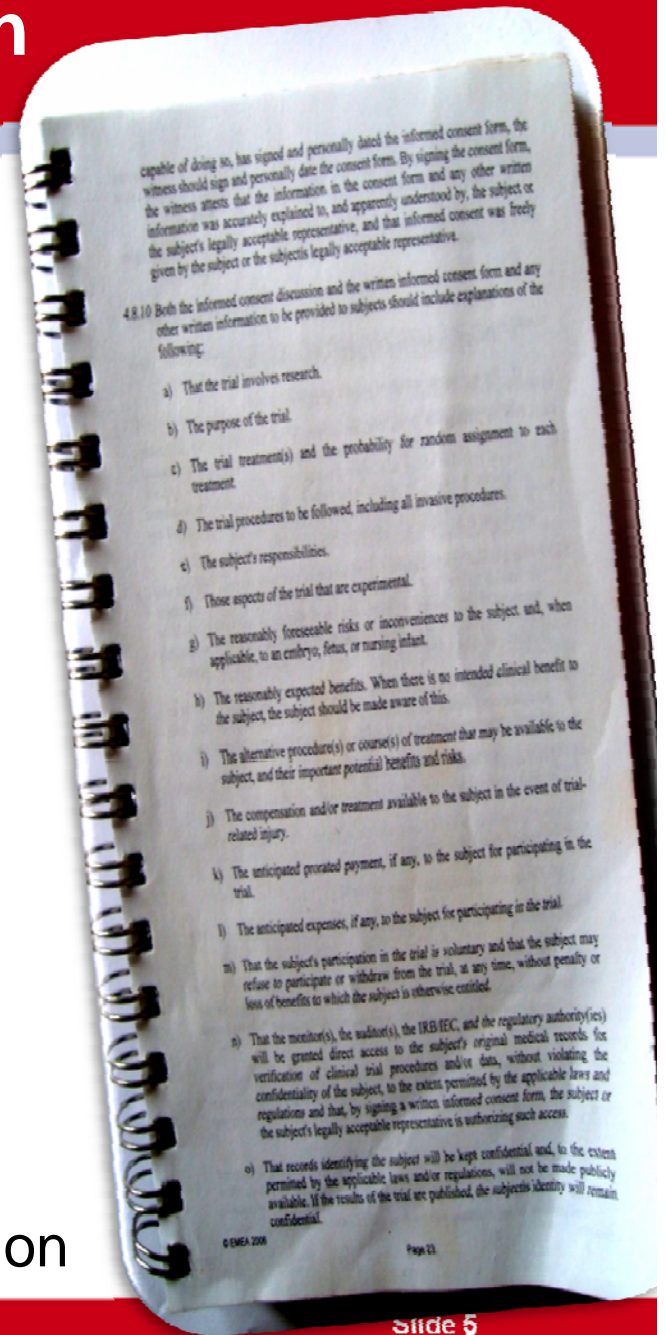
- WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI - Ethical Principles for Medical Research Involving Human Subjects
- ICH Topic E6, Guideline for Good Clinical Practice, Chapter 2 and 4:
  - Conducting the informed consent discussion
  - Required elements of discussion and written information
  - Obtain written informed consent
  - Provision of important new information
- S.I No. 190 of 2004:
  - Schedule 1: Conditions and Principles for the Protection of Clinical trial Subjects.
    - Part 3: Able to give consent
    - Part 4: Minors
    - Part 5: Incapacitated Adult



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# Informed Consent Discussion

- Informed Consent discussion and written information (Subject Information Sheet):
  - Ethical Principles, Dec. of Helsinki
  - Required elements of ICH GCP 4.8.10
- Subject Information Sheet
  - Highly controlled document:
    - Favorable opinion of Recognised EC
    - Authorisation of IMB
- Roles:
  - Investigator: Communicate and Explain
  - Subject: Assess and make informed decision



# Additional Considerations

- Consent obtained prior to any study specific procedures performed
- Consented Subjects:
  - Copy of Subject Information Sheet
  - General Practitioner informed, if Subject agreed
- Provision of important new information, timely manner



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# In Republic of Ireland.....

- Advertisement or recruitment of subjects to a Clinical Trial should not begin until the following are obtained:
  - Ethics Committee favorable opinion
  - IMB Authorisation
- Informed Consent Discussion:
  - Interview with Investigator required
  - Other staff may be involved
  - Investigator:
    - Assure Subject understood all information
    - Any questions have been answered
    - Obtain voluntary written informed consent



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# Minors



- Requirements: Part 4, Schedule 1, S.I No. 190 of 2004
- Aspects:
  - Informed consent discussion: every person with parental responsibility
  - Assent: Explicit wish of minor, who is capable of forming an opinion, after receiving information to his/her capacity, to refuse participation or be withdrawn, is considered



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# Incapacitated Adults

- Requirements: Part 5, Schedule 1, S.I No. 190 of 2004
- Incapacitated Adult: Unable by virtue of physical or mental incapacity to give informed consent
- Aspects:
  - Informed Consent discussion:
    - Legal Representative
    - Person other than person connected with the trial
  - Subject Assent



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# Inspection

- First aspect reviewed during inspection
- Interview, at least, with Principal Investigator on e.g.:
  - Informed Consent Process
  - Knowledge of required elements for informed consent discussion
  - Management of new important information



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# Inspection

- Written Informed Consent:
  - Initial written consent available, signed and dated by Subject and Investigator
  - Appropriate version of Subject Information Sheet
  - Investigator: delegated and trained
  - General Practitioner informed, if Subject agreed
  - Important new information communicated in timely manner



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# Common Deficiencies

- Initial Informed consent
- Provision of important new information (re-consent)
- Poor documentation practices



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# Initial Informed Consent

Example: The Subject Information Sheet, used in the informed consent discussion and in documenting written informed consent, was not an up to date version

- **Expectation:**
  - Subject consented with most recently 'approved' version
  - Adequate version control at site



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# Initial Informed Consent

Example: The dates upon which the Investigator and Subject signed the written informed consent were different.

- **Expectation:**
  - Other staff may be involved in the process
  - Investigator:
    - Assure Subject understood all information
    - Any questions have been answered
    - Obtain voluntary written informed consent
    - Signed and date consent form



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# Provision of Important New Information

Example: The Subject was not re-consented in a timely manner when important new information became available

- **Expectation:**

- Appropriate judgment applied, consistent with ethical principles of Declaration of Helsinki

- **Considerations:**

- To give new information at Subject's next visit, may not be appropriate in all situations
- Investigator: communicate and explain
- Subject: Assess and make informed decision



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# Provision of Important New Information

Example: Informed consent, following communication of important new information to the Subject, was not obtained by an Investigator

- **Expectation:**
  - Other staff may be involved in the process
  - Investigator:
    - Assure Subject understood all information
    - Any questions have been answered
    - Obtain voluntary written informed consent
    - Signed and date consent form



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# Poor Documentation Practices



- Common Deficiencies:
- Written Consent Form:
  - Subject or Investigator signed in the wrong place
  - Subject printed and not signed name
  - Subject not dated their own signature
- Lack of version control – cannot verify if approved form used



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# Key Messages

- Investigator's role is to act as **communicator of required information to the Subject**
- **Subject Information Sheet:**
  - **Basis for discussion**
  - **Change control at sites for new versions**
- **Investigator responsible for obtaining voluntary written informed consent**
- **Important new information should be supplied in a timely manner**



# Demonstration

- *Informed Consent Discussion*
  - *How not to perform it.....*
- *Thanks to:*
  - *Regulatory Pathways, World Health Organisation:*
    - *Dr. Liliana Chocarro*
    - *Dr. Umit Kartogluu*



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